

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

SHEN WEI (USA) INC. and)	
MEDLINE INDUSTRIES, INC.,)	
)	
Plaintiffs,)	No. 05 C 6004
)	
v.)	Judge Ronald A. Guzmán
)	
SEMPERMED USA, INC.,)	
)	
Defendant.)	

MEMORANDUM OPINION AND ORDER

Plaintiffs have sued defendant for infringing U.S. Patent No. 6,953,582. The case is before the Court for rulings on: (1) plaintiffs’ objections to Magistrate Judge Nolan’s order granting defendant’s motion to strike portions of plaintiffs’ expert witnesses’ sur-rebuttal reports; (2) defendant’s motion to strike portions of plaintiffs’ submissions in support of their motion for summary judgment and in opposition to defendant’s motion; (3) plaintiffs’ motion to strike the testimony of defendant’s expert Dr. Mark Redmond; and (4) both parties’ motions for summary judgment. For the reasons set forth below, the Court overrules plaintiff’s objections to Magistrate Judge Nolan’s ruling, grants in part and denies in part the parties’ motions to strike, denies plaintiffs’ motion for summary judgment and grants defendant’s motion for summary judgment.

Objections to Judge Nolan’s Ruling

The Court will set aside Judge Nolan’s ruling on defendant’s motion to strike only if the ruling “is clearly erroneous or contrary to law.” 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a). It is neither. The issue is not, as plaintiffs insist, whether they timely served the sur-rebuttal reports of

their experts McFadden and Wickett. Rather, it is whether the challenged portions of those reports actually constitute rebuttal testimony.

Federal Rule of Civil Procedure 26 (“Rule”) requires an expert witness to give “a complete statement of all opinions [he] will express and the basis and reasons for them” in his initial report. Fed. R. Civ. P. 26(a)(2)(B)(I). The Rule also permits experts to submit rebuttal reports but limits the contents of those reports to “evidence [that] is intended solely to contradict or rebut evidence on the same subject matter identified” in another party’s expert witness report. Fed. R. Civ. P. 26(C)(ii). In other words:

A party presents its arguments as to the issues for which it has the burden of proof in its initial expert report. And in its rebuttal expert report, it presents expert opinions refuting the arguments made by the opposing party in its initial expert report. The rebuttal expert report is no place for presenting new arguments, unless presenting those arguments is substantially justified and causes no prejudice.

Baldwin Graphic Sys., Inc. v. Siebert, Inc., No. 03 C 7713, 2005 WL 1300763, at *2 (N.D. Ill. Feb. 22, 2005).

In his rebuttal report, defense expert Redmond said plaintiffs had no evidence that: (1) Vitamin E functions the same way within the combination of substances that comprise the coating of the accused glove as it does in isolation; (2) any of the coating’s constituent substances is transferred to the wearer’s hand; or (3) any substance that may be transferred performs the skin-enhancing functions claimed in the ‘582 Patent. (Exs. Supp. Pls.’ Mem. Supp. Mot. Summ. J. & Stmt. Mat’l Facts [hereafter, “Pls.’ Exs.”], Ex. 31, Redmond Rebuttal Report ¶¶ 11, 35-36, 39-41.) Rather than refuting Redmond’s opinions with evidence plaintiffs previously proffered, Wickett and McFadden said, for the first time, in their sur-rebuttal reports that the coating of the accused glove contains substances other than Vitamin E that perform the claimed skin-enhancing functions and, when they are combined with Vitamin E, do not inhibit its skin-enhancing properties. (See Pls.’ Ex. 4, Wickett

Sur-Rebuttal Report at 10-12; Exs. Supp. Pls.’ Opp’n Sempermed’s Mot. Summ. J. & Pls.’ Resp. Def.’s Stmt. Mat’l Facts [hereafter, “Pls.’ Opp’n Exs.”], Ex. FF, McFadden Sur-Rebuttal Report at 4-5.) In addition, McFadden said, for the first time, that he had worn the accused gloves and found that they left a smooth, but not greasy, coating on his hands. (Pls.’ Opp’n Ex. FF, McFadden Sur-Rebuttal Report at 5-7.) The Court agrees with Judge Nolan that these are new opinions, not rebuttal evidence within the meaning of Rule 26.

The Court also agrees that plaintiffs’ failure to disclose these opinions earlier was not justified. From the inception of this suit through the submission of their initial expert report, plaintiffs identified only one substance in the accused glove that allegedly performs the skin-enhancing functions claimed in the ‘582 Patent: Vitamin E. (*See* Pls.’ Ex. 63, Pls.’ Answer Def.’s Interrog. No. 1; Pls.’ Ex. 3, McFadden Expert Report at 9-10, 13, 16-17.) Moreover, though they knew Vitamin E was not the only substance in the accused gloves’ coating, the McFadden’s initial expert report contains no opinions about the properties of the other substances, or the effect, if any, that they have on Vitamin E. (*See generally*, Pls.’ Ex. 3, McFadden Report.) Similarly, though he could have done a “try-on” test of the accused gloves at the beginning of the case, McFadden waited until sur-rebuttal to do so. Because plaintiffs offered no explanation for their belated production of this evidence, Judge Nolan correctly found that the delay was unjustified.

However, even unjustified delays can be excused if they do not prejudice the other party. Plaintiffs say there was no prejudice here because they gave defendant their experts’ sur-rebuttal reports before defendant took their depositions. That argument ignores the fact that defendants spent two and one-half years preparing a defense based on plaintiffs’ original representations, *i.e.*, that Vitamin E was the only substance in the accused gloves’ coating that performs the skin-enhancing functions claimed in the patent and they would not rely on evidence from their expert’s “try-on” test.

Given the circumstances, Judge Nolan's conclusion that defendant was prejudiced by plaintiffs' delay was not clearly erroneous. Plaintiffs' objections to Judge Nolan's ruling are overruled.

Motion to Strike Portions of Plaintiffs' Submissions

Defendant asks the Court to strike paragraphs 21-23 of plaintiffs' Local Rule 56.1(a) Statement of Undisputed Material Facts and paragraphs 208-210 of plaintiffs' Local Rule 56.1(b) Statement of Additional Material Facts because they are supported, in whole or in part, by the stricken sur-rebuttal evidence. The Court grants in part and denies in part the motion as follows:

(1) paragraphs 21 and 208, which are identical, will stand because the assertions in it are supported by the other evidence cited;

(2) the assertions that: (a) cetearyl alcohol, Vitamin A and Vitamin D2 Ecocalciferol have "skin-soothing, skin moisturizing, skin humectant, skin conditioning, skin medicinal, skin anti-inflammatory and skin nourishing" properties; (b) propylene glycol has skin-soothing, skin medicinal, skin anti-inflammatory and/or skin nourishing properties; and (c) Vitamin E in combination with other substances is a "skin conditioning and moisturizing substance, as well as a skin medicinal substance, a skin humectant substance, a skin nourishing substance, a skin anti-inflammatory substance, a skin emollient, and skin soothing substance" are stricken from paragraphs 22 and 209, which are identical. The remaining assertions in those paragraphs will stand.

(3) the last three sentences of paragraphs 23 and 210, which are identical and unsupported by the evidence cited, are stricken.

The Court also strikes plaintiffs' exhibits 34-36 and 37-39, which they submitted solely to support the stricken fact assertions, and any arguments they make in their summary judgment briefs that are based on the stricken assertions or exhibits.

Defendant also asks the Court to strike plaintiff's exhibit 32, a list of the ingredients in the Vitamin E lotion used in the accused gloves produced by third party Sintal because plaintiffs obtained it after the close of discovery. Plaintiffs say the motion should be denied because, though they

received the document ten days after discovery closed, they had requested it well before. Given their diligence in seeking discovery from Sintal, plaintiffs say the document should remain in the record.

The record does not bear out plaintiffs' claims of diligence. Earlier this year, the Court extended the discovery deadline from March 17 to April 18, 2008, in part, so plaintiffs could "complete discovery pursuant to [their] subpoena to Sintal." (*See* Joint Mot. Modify Discovery Schedule of 3/4/08 at 2; Minute Order of 3/21/08.) Plaintiffs then waited until April 15, 2008, three days before the new cut-off date, to depose Sintal. (Pls.' Resp. Opp'n Sempermed's Mot. Strike Specific Sections Pls.' Mot. Summ. J., Opp'n Sempermed's Mot. Summ. J. & Statement Undisputed Material Facts at 5.) Not surprisingly, during the deposition, plaintiffs learned that Sintal had a document – the "recipe" for the Vitamin E lotion used in the accused gloves – that it should have, but had not, produced. (*Id.*) Despite the looming discovery deadline, plaintiffs did not file a motion to compel or ask the Court to extend the discovery deadline. (*Id.*) Instead, they simply waited for Sintal to produce the document. (*Id.*) Because the record belies plaintiffs' claim that they diligently sought the document, their exhibit 32, the Court strikes it from the record.

Motion to Strike Portions of Defense Expert Redmond's Testimony

Plaintiffs say defense expert Redmond is not qualified to render many of the opinions contained in his reports because he has no expertise in glove manufacturing or patent law. (*See* Exs. Supp. Pls.' Mot. Strike Testimony Def.'s Expert Dr. Mark Redmond, Ex. 3, Redmond Expert Report ¶¶ 3-7, 12 (stating that he has a Ph.D in biochemistry, has spent twenty years in the biotechnology industry and is an expert in "the biochemistry and action of natural ingredients," including "oat extracts and [their] utilization in cosmetics, personal care, and therapeutic applications" but not "in the manufacture of gloves" or "the field of patent law").) The Court agrees that Redmond's lack of

expertise in those areas bars him from offering opinions on enablement, best mode, adequacy of written description and the glove manufacturing process. But he can testify about, among other things, how a person skilled in the art of the biochemistry of natural ingredients and their use in cosmetic, personal care and therapeutic applications would interpret the terms used in the '582 Patent and others to describe skin-enhancing functions. With these principles in mind, the Court turns to the contested statements.

The Expert Report

Defendant asks the Court to strike, in whole or part, paragraphs 17-32, 36-41, 86-95, 97-152, 154-57, 178, 184 and 214-48 from Redmond's expert report. The Court strikes:

- Paragraph 17: the first paragraph; the second paragraph on page 6 (starting with "Thus, 'SKIN CONDITIONING SUBSTANCE'" and ending with "related to aloe vera"); and the first sentence of the third paragraph;
- Paragraph 18: the last paragraph;
- Paragraph 25: the first paragraph;
- Paragraph 27: the last sentence;
- Paragraph 28 in its entirety;
- Paragraph 29: the last sentence;
- Paragraph 31: the last sentence;
- Paragraph 32: the last sentence;
- Paragraphs 36-41, 86 and 87 in their entirety;
- Paragraph 88: the words "I note also that the '154 patent never describes using substances which are" from the first sentence; the second sentence in its entirety; the third sentence in its entirety; and the last sentence in its entirety;
- Paragraphs 90-93 in their entirety;

- Paragraph 94: the last two sentences;
- Paragraph 95: the words “The ‘154 specification discloses a substance which dissolves to form a water” from the first sentence; and the second sentence in its entirety;
- Paragraph 97: the last sentence;
- Paragraphs 98-100 in their entirety;
- Paragraph 101: the words “The ‘154 specification discloses a substance which dissolves to form a water” from the first sentence; and the second sentence in its entirety;
- Paragraphs 102-05 in their entirety;
- Paragraph 106: all language except “Perspiration will always contact, wet or moisturize whatever is found on the inside of a latex glove”;
- Paragraphs 107-08 in their entirety;
- Paragraph 109: the first sentence;
- Paragraph 110: the words “Thus, the claims of the ‘582 patent expand the invention to cover” and “such that the substances covered by the claims extend to substances which do not dissolve in water, but which” from the first sentence; and the second sentence in its entirety;
- Paragraph 111: the first sentence;
- Paragraph 113: the last sentence;
- Paragraph 114: the last sentence;
- Paragraphs 115-16 in their entirety;
- Paragraph 117: the words “functional,” “so” and “so as to render all of the claims vague and indefinite, and thus unpatentable under 35 U.S.C. § 112” from the first sentence;
- Paragraph 118 in its entirety;
- Paragraph 120 in its entirety;

- Paragraph 121: the words “I suspect that the reason the ‘582 patent claims were written this way is because” from the first sentence; the third sentence in its entirety;
- Paragraph 122: all language except the second sentence;
- Paragraphs 123-32 in their entirety;
- Paragraph 133: the last two sentences;
- Paragraph 134: the last two sentences;
- Paragraph 135: the first sentence; the second paragraph; the last sentence;
- Paragraph 136: the last sentence;
- Paragraph 137: the second sentence;
- Paragraphs 138 and 139 in their entirety;
- Paragraph 140: the language “as the ‘154 patent specification itself emphasizes” from the last sentence;
- Paragraph 141: the language “but as I have said above that is not the test for adequate description as I understand it”;
- Paragraphs 142-43 in their entirety;
- Paragraphs 145-46 in their entirety;
- Paragraph 147: the first sentence;
- Paragraphs 148-57 in their entirety;
- Paragraph 178: the last sentence;
- Paragraph 184: the words “and/or would have rendered” and “obvious” from the third sentence;
- Paragraphs 214-24 in their entirety;
- Paragraph 225: all language except the last sentence;
- Paragraphs 226-27 in their entirety;

-Paragraph 228: the words “Yet, further, to the extent that the ‘582 patent uses vague functional claim language” from the second sentence;

-Paragraph 229: the first sentence;

-Paragraph 230: the words “adds to the obvious nature of using a natural extract in a latex glove” from the first sentence; the words “was obvious and” from the second sentence;

-Paragraphs 232-38 in their entirety;

-Paragraphs 240-48 in their entirety.

In all other respects, Redmond’s expert report will stand as written.

The Supplemental Report

Defendant also asks the Court to strike, in whole or part, paragraphs 12, 24 and 27 of Redmond’s supplemental report (Exs. Supp. Pls.’ Mot. Strike Testimony Def.’s Expert Dr. Mark Redmond, Ex. 4). The Court strikes:

-Paragraphs 12 and 24 in their entirety;

-Paragraph 27: all language except “I also note the fact silicon and spearmint oil are both recognized and/or claimed skin conditioning substances.”

In all other respects, Redmond’s supplemental report will stand as written.

The Sur-Rebuttal Report

Finally, defendant asks the Court to strike paragraphs 12-16, 24-117, 123-24, 128-29, 131 and 134 of Redmond’s sur-rebuttal report (Exs. Supp. Pls.’ Mot. Strike Testimony Def.’s Expert Dr. Mark Redmond, Ex. 5). The Court strikes:

-Paragraph 12 in its entirety;

-Paragraph 13: the words “and to determine what is claimed and what is not” from the penultimate sentence;

- Paragraphs 15 and 16 in their entirety;
- Paragraph 24: the second sentence; and the last sentence;
- Paragraphs 25 and 26 in their entirety;
- Paragraph 27: the first sentence; the words “These” and “such that the substances covered by the claims extend to substances which do not dissolve in water” from the second sentence; and the last sentence in its entirety;
- Paragraph 28 in its entirety;
- Paragraph 29: the first sentence; and the last sentence;
- Paragraph 30: the words “in order to have full disclosure” from the last sentence;
- Paragraph 31 in its entirety;
- Paragraph 32: the first sentence;
- Paragraph 35: the words after “functional preparations” in the first sentence; and the words “after reading the disclosure of the ‘154 and ‘582 patents” from the last sentence;
- Paragraph 36: the last sentence;
- Paragraphs 37-39 in their entirety;
- Paragraph 40: the words “as claimed in Claim 3” from the first sentence;
- Paragraph 49: the words “(also theoretically covered by the claims of the ‘582 patent)”;
- Paragraphs 51-54 in their entirety;
- Paragraph 55: the first sentence; the words “nor the ‘154 or ‘582 patents” from the last sentence;
- Paragraph 56 in its entirety;
- Paragraph 57: the first two sentences; and the last sentence;
- Paragraph 58: the last sentence;
- Paragraph 59: the words “to the claimed subject matter of the ‘582 patent”;

- Paragraphs 61 and 62 in their entirety;
- Paragraph 65 in its entirety;
- Paragraph 66: the words “such as those claimed in the ‘582 patent” from the first sentence; and the last sentence in its entirety;
- Paragraph 67 in its entirety;
- Paragraph 68: the last sentence;
- Paragraph 72: the words “and claim validation”;
- Paragraphs 78-83 in their entirety;
- Paragraphs 86 and 87 in their entirety;
- Paragraph 88: the first sentence;
- Paragraph 90: the words “as to the ‘582 and ‘154 patents [sic] failing to provide”;
- Paragraphs 91 and 92 in their entirety;
- Paragraph 94 in its entirety;
- Paragraph 96-99 in their entirety;
- Paragraph 100: the first sentence;
- Paragraphs 101-04 in their entirety;
- Paragraph 105: the words “so that one would not know whether the functional term is satisfied or not”;
- Paragraph 107 in its entirety;
- Paragraph 109: the words “however it is not clear to me how an emollient contained in the glove claimed in the ‘582 patent is directed to be rubbed-in”; and the last sentence in its entirety;
- Paragraph 110 in its entirety;
- Paragraph 112: the last sentence;
- Paragraph 113 in its entirety;

-Paragraph 115: the words “which appears as a limitation in claims 46 and 50” from the second sentence; and the last sentence in its entirety;

-Paragraph 116: the words “necessary so as to permit one to determine when a claim is infringed, and when it is not”;

-Paragraph 117: the words “and rendered obvious by” and “or the Ostar® manufacturing process”;

-Paragraph 123: the first sentence; the last sentence;

-Paragraph 124 in its entirety;

-Paragraphs 127 and 128 in their entirety;

-Paragraph 129: the first sentence; the words from the third sentence “and the limitation to hair and fabric conditioners is contrary to the teaching of the ‘943 patent”;

-Paragraph 131 in its entirety;

-Paragraph 134: the first sentence; the last sentence;

In all other respects, Redmond’s sur-rebuttal report will stand as written.

Summary Judgment

Plaintiff Shen Wei is a manufacturer of disposable gloves that are distributed by plaintiff Medline. (Def.’s Corrected Resp. Pls.’ Local Rule 56.1(a) Stmt. Material Facts [hereafter, “Def.’s Resp. Pls.’ LR 56.1(a)”] ¶¶ 1, 3-4.) Shen Wei is the owner of U.S. Patent No. 6,953,582 (“the ‘582 Patent”), entitled “Skin-Enhancing Glove and Method of Manufacture.” (Def.’s Resp. Pls.’ LR 56.1(a) ¶ 8; Pls.’ Exs. Supp. Mem. Supp. Mot. Summ. J. [hereafter, “Pls.’ Exs.”], Ex. 1, ‘582 Patent at 1.) The ‘582 Patent is a descendent of another Shen Wei patent, U.S. Patent No. 6,274,154 (“the ‘154 Patent”), the application for which was filed on April 7, 1999. (Pls.’ Ex. 1, ‘582 Patent at 1.)

Defendant Sempermed sells disposable gloves under the name Polymed® TLC (“Polymed gloves”). (Def.’s Resp. Pls.’ LR 56.1(a) ¶ 5.) Plaintiffs have sued defendant for patent infringement and contend that the Polymed gloves infringe claims 1-5, 7, 13-15, 22, 25-29, 34, 45-47 and 49-51 of the ‘582 Patent. (See Am. Compl.; Pls.’ Opp’n Def.’s Mot. Summ. J. at 2 n.1.) Sempermed has countersued for a declaration that the Polymed gloves do not infringe and the claims of the ‘582 Patent are invalid and unenforceable. (See Third Am. Countercl.) Both parties seek summary judgment on their claims.

To prevail on a summary judgment motion, “the pleadings, the discovery and disclosure materials on file, and any affidavits [must] show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). At this stage, we do not weigh evidence or determine the truth of the matters asserted. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). We view all evidence and draw all inferences in favor of the non-moving party. *Michas v. Health Cost Controls of Ill., Inc.*, 209 F.3d 687, 692 (7th Cir. 2000). “In considering cross-motions for summary judgment, we are obliged to view all facts and draw all reasonable inferences in a light most favorable to the party against whom the motion under consideration is made.” *Gazarkiewicz v. Town of Kingsford Heights*, 359 F.3d 933, 939 (7th Cir. 2004). Summary judgment should be granted only when the record as a whole establishes that no reasonable jury could find for the non-moving party, *Michas* 209 F.3d at 692, and is “as appropriate in a patent case as it is in any other.” *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 672 (Fed. Cir. 1990). Because defendant’s motion, if successful, will moot plaintiffs’ motion, the Court will start with it, viewing the evidence in the light most favorable to plaintiffs.

I. Anticipation

A. Article Claims

Defendant argues that claims 13-16, 18, 22, 27 and 48-51 (“article claims”)¹ of the ‘582 Patent are anticipated by the prior art Ostar® glove. A claim is anticipated if “each [of its] element[s] . . . is found, either expressly or under principles of inherency, in a single prior art reference,” or “the claimed invention was previously known or embodied in a single prior art device or practice.” *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992). Patents are presumed to be valid. 35 U.S.C. § 282. To overcome this presumption, defendant must prove anticipation by “clear and convincing evidence.” *See Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1345-46 (Fed. Cir. 1999).

Plaintiffs admit that Ostar® gloves were sold in the United States more than two years before April 7, 1999, the filing date to which plaintiffs say the ‘582 Patent is entitled. (*See* Pls.’ Corrected Resp. Def.’s Corrected Stmt. Material Facts Supp. Def.’s Mot. Summ. J. [hereafter, “Pls.’ Resp. Def.’s Stmt. Facts”] ¶ 30; Pls.’ LR 56.1(a) Stmt. Facts ¶ 122; Pls.’ Ex. 1, ‘582 Patent at 1.) However, they argue that defendant has not offered clear and convincing evidence that: (1) the interior coating of the Ostar® glove contained a skin-enhancing substance, *i.e.*, “a skin-moisturizing substance,” as required by claims 13, 15 and 16; “a skin-moisturizing substance [that] includes a medicinal substance,” as required by claim 14; “a skin softening substance,” as required by claim 48; “a skin nourishing substance,” as required by claim 49; “a skin emollient substance,” as required by claim 50; or “a skin anti-inflammatory substance,” as required by claim 51; or (2) the coating was

¹Claims 23 and 26 are also article claims but, because they claim a glove manufactured according to methods claimed in the Patent, the Court addresses them with the method claims.

“moistened only by perspiration of the hand,” as required by claims 18, 22 and 27. (Pls.’ Mem. Supp. Mot. Summ. J. at 14-24; Pls.’ Opp’n Sempermed’s Mot. Summ. J. at 2-13.)

1. Skin-Enhancing Substance

Defendants contend that the skin-enhancing substance in the coating of the Ostar® glove is Arriveen. Plaintiffs say the record does not clearly establish that the coating of the glove actually contained Arriveen or that Arriveen has any skin-enhancing effects.

With respect to the first issue, the record contains the following undisputed facts. From 1996 through October 1998, Ultravena Industries, which sold the Ostar® gloves, purchased an oat powder blend called 4DARR from Canamino. (Pls.’ Resp. Def.’s Stmt. Facts ¶¶ 14-15; Exs. Supp. Def.’s Corrected Stmt. Material Facts [hereafter, “Def.’s Exs.”], Exs. 31 & 33, Ultravena Purchase Orders to Canamino for “Ostar 4DARR blended powder” dated January 3, 1996 & October 5, 1996, respectively; *id.*, Ex. 34, Canamino Sales Order to Ultravena for “4DARR Blended Powder” dated April 8, 1998.) The 4DARR powder was ninety-six percent oat starch and four percent Arriveen, an oat extract. (Def.’s Corrected Stmt. Material Facts Supp. Mot. Summ. J. [hereafter, “Def.’s Stmt. Facts”] ¶ 24; Pls.’ Resp. Def.’s Stmt. Facts ¶ 24.) Canamino shipped the 4DARR powder either to Ultravena’s glove manufacturer in Malaysia, Perusahaan Pelindung Getah (M) Sdn Bhd (“PPG”), or to Ultravena’s Malaysian representative, MRY & Associates (also called “Contract Latex Dippers”). (Pls.’ Resp. Def.’s Stmt. Facts ¶¶ 28-29; Def.’s Exs. 31 & 33, Ultravena Purchase Orders to Canamino for “Ostar 4DARR blended powder” to be shipped to MRY; Def.’s Ex. 34, Canamino Sale Order to Ultravena for “4DARR Blended Powder” to be shipped to Contract Latex Dippers.)

Lim Kwee Shyan, who was the general manager of PPG at the time, said that PPG used the 4DARR powder that it received to coat the interior of the Ostar® gloves. (Def.’s Ex. 35, Lim Sur-
Rebuttal Report ¶ 9; *see* Def.’s Exs. 31 & 33, Ultravena Purchase Orders for 4DARR; Def.’s Ex. 34,

Canamino Invoice for 4DARR.) Redmond, who was been an officer of Canamino's parent company, Ceapro, since 1996, said the same thing. (Def.'s Ex. 4, Redmond Expert Report ¶ 3; Def.'s Ex. 13, Redmond Dep. at 85-87, 188.) Moreover, Daniel Olson, who was an officer or employee of Ultravena in 1996, testified without contradiction that he did "quality control checks on the product that was sitting in Malaysia" and found that the gloves were coated with 4DARR. (Def.'s Exs. Supp. Opp'n Pls.' Mot. Summ. J. [hereafter, "Def.'s Opp'n Exs."], Ex. 95, D. Olson Dep. at 48.)

Though undisputed, plaintiffs contend that this evidence is nullified by Redmond and Lim's admissions that they did not test the gloves for the presence of Arriveen. (*See* Pls.' LR 56.1(a) Stmt. ¶¶ 58-59.) That argument is premised on the faulty assumptions that: (1) direct evidence always trumps circumstantial evidence; (2) direct evidence is required to prove invalidity; (3) there is no direct evidence that the Ostar® gloves contained Arriveen; and (4) there is no reasonable explanation for the defense experts' failure to test the accused gloves for Arriveen. The Federal Circuit has rejected the first two assumptions, the undisputed testimony of Daniel Olson refutes the third, and the undisputed fact that "the production of Arriveen completely ceased by October 1998," six months before Shen Wei filed the '154 Patent application and six years before it filed this suit, refutes the last. *See Checkpoint Systems, Inc. v. All-Tag Sec. S.A.*, 412 F.3d 1331, 1339 (Fed. Cir. 2005) (stating that "[p]hysical, documentary, or circumstantial evidence, or reliable testimony from individuals other than the alleged inventor or an interested party" can provide corroboration of invalidity testimony); *Fuji Photo Film Co., Ltd. v. Jazz Photo Corp.*, 394 F.3d 1368, 1374 (Fed. Cir. 2005) ("Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence." (quotation omitted)); (Def.'s Opp'n Ex. 95, D. Olson Dep. at 48; Pls.' Resp. Def.'s Stmt. Facts ¶ 17).

In short, the record is replete with evidence that the coating of the Ostar® gloves actually contained Arriveen, and none at all that suggests it did not. Consequently, the Court finds that there is clear and convincing evidence that the Ostar® gloves contained Arriveen.

The next issue is whether Arriveen contains a skin-enhancing substance. Plaintiffs say it does not because the record shows that skin considerations played no role in Ultravena's decision to develop the glove. (*See* Pls.' LR 56.1(a) Stmt. ¶¶ 29-30.) As support, plaintiffs cite the deposition testimony of Larry Olson, Joseph Neuser and Bruce Robertson, all of whom were involved in developing the glove, and various advertisements for it. (*Id.*) Rather than supporting plaintiffs' argument, however, the evidence they cite contradicts it. Olson, Neuser and Robertson all testified that the Ostar® glove was developed to eliminate cornstarch-related problems in a way that was good for the wearer's skin. (*See* Pls.' Ex. 50, L. Olson Dep. at 170-71; Pls.' Ex. 51, Neuser Dep. at 77-80; Pls.' Ex. 52, Robertson Dep. at 30-32.) Similarly, each of the advertisements plaintiffs cite characterizes the Ostar® gloves as skin-enhancing. (*See* Pls.' Ex. 5 at CGS000017 (saying "Protect and heal your skin . . . [sic] With Ostar® gloves" & "Corn Starch can damage your skin, Oat Powder is good for your skin"); *id.* at CGS000020 ("Oat powder will help heal dry hands and damaged skin"); Pls.' Ex. 6 at CGS000012 ("Use Ostar's® exclusive oat powdered gloves. . . [sic] to heal & protect the ultimate barrier – Your Skin!"); *id.* at CGS000013 ("Ostar® Latex Exam Gloves are the only gloves available today which, in place of corn starch, use purified extracts of colloidal oatmeal Purified extracts of oats are clinically proven to reduce redness, and have excellent moisturizing capabilities."); Pls.' Ex. 7 at CGS000015 ("Natural oat powder is a purified form of colloidal oats, which is a known skin protectant."); Pls.' Ex. 8 at CGS000674 (stating that Arriveen "[r]evitalizes dry, irritated skin"); Pls.' Ex. 9 at CGS000027 ("The daily use of Ostar Gloves will help to combat skin irritation and dryness.")) Because the evidence does not suggest that eliminating corn starch-

related health problems was the only reason for development of the Ostar® glove, it also does not support the inference that plaintiffs seek to draw from it – that Arriveen has no skin-enhancing properties.²

The question that remains, of course, is whether the record, viewed favorably to plaintiffs, clearly shows that Arriveen is skin-enhancing. Redmond testified that it is because Arriveen contains oat oil which, in turn, contains Vitamin E. (*See* Def.’s Ex. 13, Redmond Dep. at 189-90). Plaintiffs admit that Arriveen contains oil. (Pls.’ Resp. Def.’s Stmt. Facts ¶¶ 19, 21.) They contend, however, that the specification for 4DARR refutes the assertion that the oil in Arriveen is oat oil.

That specification, as plaintiffs note, does not list oat oil as an ingredient of 4DARR. (*See* Pls.’ Resp. Def.’s Stmt. Facts ¶ 26; Pls.’ Opp’n Ex. AA, 4DARR Specification.) That omission would be damning if the specification said 4DARR contains no oil or contains oil only from a source other than oats. But it does not. Rather, it says that 4DARR has an “[o]il content” of “0.1-1.0%.” (Pls.’ Opp’n Ex. AA, 4DARR Specification). Given the undisputed fact that Arriveen was extracted from oats, it is not reasonable to infer from the 4DARR specification’s generic reference to “oil” that Arriveen contains oil solely from another source. Because the specification is the only evidence plaintiffs cite to dispute Redmond’s testimony that Arriveen contains oat oil (*see* Pls.’ Resp. Def.’s Stmt. Facts ¶ 26), his assertion stands un rebutted.

Even if there is oat oil in Arriveen, plaintiffs argue that there is still no evidence that the oat oil contains Vitamin E. When Redmond testified about the vitamin content of oat oil, plaintiffs say

²Moreover, even if the evidence suggested that skin-enhancement played no role in Ultravena’s decision, that fact would not necessarily foreclose defendant’s anticipation argument because it is the function of the glove, not the motivation of its maker, that matters for anticipation. *Atlas Powder*, 190 F.3d at 1347 (“[I]f the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.”).

he was referring solely to oat oil that Ceapro currently sells. (*Id.*) Because that oil is obtained through extraction methods different from the one used to obtain Arriveen, plaintiffs contend that Redmond's testimony does not extend to Arriveen.

However, as the following colloquy demonstrates, Redmond was not testifying solely about Ceapro's current products when he said that oat oil contains Vitamin E:

A. . . . In the course of my working with oats, oat extracts, over the last 15 years I have conducted a number of extractions and studies on oat oil. Ceapro currently sells an oat oil into the commercial market. We actually have also just introduced an ethanolic oil or an oil extracted from oats using ethanol. In every case, when you examine the oat oil, it contains Vitamin E. . . .

Q. Okay. But do you know – I mean have you performed any studies to show that the blended oat powder that was sold to Ultravena actually contained Vitamin E?

A. No. We did studies which showed that the powder contained oil and we know that oat oil contains Vitamin E.

Q. You have done studies – that which powder contains Vitamin E?

A. Arriveen powder contains oat oil, and oat oil in every case I have looked at contains Vitamin E.

(Def.'s Ex. 13, Redmond Dep. at 189-90.) Rather, he was testifying about studies he had conducted on oat extracts, including Arriveen, and oat oil throughout his career with Ceapro.

Second, even if Redmond had been testifying only about the ethanolic oat oil Ceapro currently sells, his testimony about its Vitamin E content would apply equally to Arriveen. Redmond testified that the process for obtaining the current ethanolic oil is virtually the same as that used to obtain Arriveen:

Q. You said Ceapro, now they sell oat oil?

A. Yes, we sell an oat oil extracted by supercritical extraction and recently we began to sample into the market an oat oil produced by the ethanolic extraction of oil from oats. So it would be similar process to the Arriveen

process with the exception we go one step further and concentrate the oil from the extract by removing the ethanol component.

(*Id.* at 190; *see* Pls.’ Resp. Def.’s Facts ¶ 21 (admitting that Arriveen was obtained through an ethanol extraction process).) The additional step in the current process, removing the ethanol from the extracted oil, would change the *amount* of each ingredient in the oil but would not change the identity of those ingredients. *See* McGraw-Hill’s Access Science Encyclopedia of Science & Technology Online, <http://www.accessscience.com/popup.aspx?id=21612&name=def> (defining concentrate as “increas[ing] the amount of a dissolved substance by evaporation.”). Consequently, the ethanolic oat oil Ceapro now sells has the same ingredients, albeit in different amounts, as the oat oil in Arriveen. Plaintiffs do not dispute that the ethanolic oat oil contains Vitamin E. (Pls.’ Resp. Def.’s Stmt. Facts ¶¶ 26-27; Def.’s Ex. 13, Redmond Dep. at 211-13; Def.’s Ex. 30, Laboratory Test Results at 12887.) Thus, the record clearly establishes that the oat oil in Arriveen contains Vitamin E.

The last question is whether there is clear and convincing evidence that Vitamin E performs the skin-enhancing functions claimed in the Patent. Plaintiffs, whose version of the facts controls for this motion, say that it does: “Vitamin E . . . is a skin conditioning and moisturizing substance, as well as a skin medicinal substance, a skin humectant substance, a skin nourishing substance, a skin anti-inflammatory substance, a skin emollient, and skin soothing substance.” (Pls.’ LR 56.1(a) Stmt. ¶ 22.)

2. Moistened Only by Perspiration

Claims 18, 22 and 27 claim gloves in which the coating or preparation is moistened only by perspiration from the wearer’s hand. Defendant says that is true of the Ostar® glove (*see* Def.’s Stmt. Facts ¶ 49), but it also says, without contradiction by plaintiffs, that healthcare professionals normally wash their hands before donning gloves. (*Id.* ¶ 89; Pls.’ Resp. Def.’s Stmt. Facts ¶ 89; *see* Def.’s Ex.

69, Redmond Rebuttal Report at 12-13.) Given the hand-washing practice, there is no way to ensure that perspiration will be the only moisture to contact the coating which, literally construed, is what the limitation requires. Thus, to be meaningful, the limitation cannot be interpreted literally. *See Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 885 (Fed. Cir. 2008) (instructing courts to interpret claims “with an eye toward giving effect to all [of their] terms” (quotation omitted)).

Moreover, because claims 18 and 22 incorporate the elements of claim 13, the limitation has to mean something more than “the coating absorbs moisture from perspiration,” which appears in claim 13. That leaves two possible meanings, that: the coating/preparation absorbs moisture only from perspiration and not from any other source, *i.e.*, water; or perspiration is the only source of moisture required to moisten the coating/preparation.

The specification supports the latter. With respect to moistening, it states:

[T]he present invention may be embodied to alternatively or additionally use any other skin-soothing or skin-moisturizing substance or mixture that can be dried onto the inside of a glove and that, in the dry form, is mixed with moisture that consists only of perspiration from a hand during wearing of the glove and moisturizes the hand.

(Pls.’ Ex. 1, ‘582 Patent, Col. 8, ll. 28-34.) That passage, which is the only discussion of the moistening process in the specification, addresses the source of the moisture that mixes with the coating, not the coating’s ability to absorb moisture from various sources. (*See id.*, Abstract (“A protective glove includes a coating of dehydrated material [which, when] in contact with perspiration from a hand wearing the glove, soothes the hand.”).) Moreover, the specification’s discussion about Aloe Vera shows that the Patent does not distinguish between moisture from perspiration and moisture from any other source:

. . . Aloe Vera is soluble in water and contains non-detectable oil content.

Aloe Vera glove retains the characteristic of a disposable glove without any visible modification, and is easy and convenient to use. The affiliation between Aloe Vera

and the glove surface is through a force provided by dehydration. Such affiliation is loosened when sweat dissolves Aloe Vera. The longer a glove is worn, the more likely the hand will sweat, and consequently more Aloe Vera will be dissolved and disassociated from the glove surface, and be applied to hand. The active ingredients in Aloe Vera can then condition hand skin and prevent microorganisms from growing under the wet condition.

(*Id.*, Col. 3, l. 59-Col. 4, l. 4.) Given the language of the specification, the Court holds that the limitations of claim 18 (“the coating is to be moistened only by perspiration of the hand”), claim 22 (“the coating is moistened only by perspiration from the hand”) and claim 27 (“the dehydrated preparation is to be moistened only by perspiration from the hand”) mean that perspiration is the only source of moisture required to moisten the coating.

The next question is whether the Ostar® glove contains this limitation as the Court construes it. The record contains clear, convincing and undisputed evidence that it does. (*See* Def.’s Ex 4, Redmond Expert Report at 51 (“The Ostar® Glove coating is in direct contact with the skin. As the body perspires, body exudates are released which interact with the powder, solubilizing and releasing active ingredients onto the skin surface.”); *id.* at 54 (“I note from personal experience that the Ostar® Glove absorbs perspiration and forms a skin-moisturizing substance on the hand of the wearer.”); Def.’s Ex., 36, L. Olson Decl. ¶ 22 (“After wearing the [Ostar®] gloves for a short period of time, I noticed that the oat starch extract coating absorbed, and was moisturized by, perspiration from my hands.”); Def.’s Ex. 37, Lim Decl. ¶ 22 (“As is common with latex gloves, my hands started to perspire after wearing the Ostar gloves for a short time. The perspiration mixed with the oat starch extract coating to form a gel-like creamy moisturizing substance that coated my hands.”); Def.’s Ex. 56, Lim Report at 20 (“I, through my own personal observation, as well as the observations of others, note that the oat starch extract of the Ostar® Glove absorbed perspiration from the hand of the wearer to form a moist skin-conditioning substance that moisturized the hand of the wearer.”); Def.’s Ex. 82,

Wickett Rebuttal Report at 11-16 (arguing that the Ostar® glove does not invalidate the ‘582 Patent for a number of reasons, none of which is the moistening process); Def.’s Ex. 86, McFadden Rebuttal Report at 13-22 (same); Pls.’ Ex. 13, D. Olson Dep. at 167 (stating that the coating of the Ostar® Glove “absorbed perspiration from the hand of the wearer to form a moist skin-conditioning substance”).

B. Method Claims

Defendant also argues that claims 1-12, 23, 25-26, 28-29, 33-35, 44-47 (“method claims”)³ of the ‘582 Patent are anticipated by the Ostar® manufacturing process. Claim 1 is an independent claim from which claims 2-12, 23, 25-26 and 28-29 depend. It claims:

A method . . . comprising the acts of:

applying a preparation onto a surface of a fluid-impermeable disposable glove, the preparation including a skin-conditioning substance and a liquid carrier, wherein the skin-conditioning substance comprises a skin-moisturizing substance, the surface of the glove to face a hand during wearing of the glove on the hand, the surface hereinafter referred to as interior surface; and

evaporating the liquid carrier from the preparation to form a dry dehydrated preparation attached to the interior surface of the glove, so that the dehydrated preparation contacts the hand during wearing of the glove on the hand.

Plaintiffs admit that the Ostar® gloves were manufactured through a continuous, chain-dipping line process comprised of the following steps: (1) forming the gloves on hand-shaped formers; (2) dipping the formers into a wet-slurry preparation of oat powder and water; (3) drying the slurry by passing the gloves through an oven, which dehydrates the preparation and makes it dry to the touch; and (4) stripping the gloves from the formers, so that the coated surface becomes the inside of the glove and the uncoated surface becomes the outside. (Pls.’ Resp. Def.’s Stmt. Facts ¶¶ 40, 43-

³See n.1.

46.) They also admit that a document generally depicting the Ostar® process (“manufacturing document”) was published in 1997. (*Id.* ¶ 41.)

They contend, however, that the manufacturing document is not enabling because it does not disclose the specific parameters – the temperatures of the slurry tank and oven, for example – of the Ostar® process. *See Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1082 (Fed. Cir. 2008) (“An anticipating reference must be enabling; that is, the description must be such that a person of ordinary skill in the field of the invention can practice the subject matter based on the reference, without undue experimentation.”); (Pls.’ Ex. 61, Lim Dep. at 107-10 (testifying that the manufacturing document does not disclose the slurry temperature, the concentration of oat starch, the kind of anti-bacterial agents or the drying temperature used to make Ostar® gloves)). But Lim, whose expertise in the art of making latex gloves is conceded by plaintiffs (*see* Pls.’ Stmt. Add’l Material Facts ¶ 222), said that a person of ordinary skill in that art would easily be able to determine those parameters. (Def.’s Ex. 10, Lim Dep. at 124-25.) According to Lim, latex glove makers continually adjust parameters because different coating materials, and even different grades of the same coating material, react differently to the same conditions. (Def.’s Ex. 56, Lim Expert Report at 13-15.) Plaintiffs offer no evidence to refute Lim’s testimony. (*See* Pls.’ Resp. Def.’s Stmt. Facts ¶¶ 40-41; Def.’s Ex. 86, McFadden Rebuttal Report at 22-24.) In fact, the testimony of the inventor, Belle Chou, and plaintiffs’ expert, McFadden, supports it. (*See* Pls.’ Stmt. Add’l Material Facts ¶ 223; Def.’s Ex. 86, McFadden Rebuttal Report at 8 (“It was a common practice in the glove development and manufacturing field [in 1999] to run small batches of gloves with alternative components to verify the components’ suitability.”); *id.* at 10 (“I believe that the amount of experimentation that would be required to make gloves using skin-conditioning substances other than aloe vera would be considered routine by those skilled in the art of glove making.”); Pls.’ Ex. 76, McFadden Decl. ¶ 8 (same); Pls.’

Ex. 75, Chou Decl. ¶ 7 (“I believe that the performance of other substances beneficial to the skin would be predictable in these gloves. . . . [R]outine batch runs would have quickly confirmed that a substance other than aloe vera would have been suitable.”).) Given the undisputed evidence, the Court finds that the manufacturing document sufficiently disclosed the Ostar® manufacturing process to constitute a prior art reference.

The next question is whether the process disclosed by the manufacturing document contains all of the elements of the method claims. Plaintiffs admit that it does, with respect to:

Claim 1 (independent method claim);

Claim 5 (dependent claim adding to claim 1 the limitation “wherein the glove is made from a natural rubber latex”);

Claim 6 (dependent claim adding to claim 1 the limitation “wherein the glove is made of a single layer prior to the applying step”);

Claim 7 (dependent claim adding the limitation “wherein the liquid carrier is water”);

Claim 11 (dependent claim adding the limitation “wherein prior to the applying step, arranging the glove inside out, whereby the interior surface of the glove faces outward”);

Claim 12 (dependent claim adding to claim 11 the limitation “wherein the glove is turned right side out after the evaporating step”);

Claim 23 (dependent article claim claiming “[a] glove manufactured according to claim 6 [which depends from claim 1]”).

Claim 26 (dependent article claim claiming “[a] glove manufactured according to claim 1”).

(*See* Pls.’ Resp. Def.’s Stmt. Facts ¶¶ 43-45; Pls.’ Opp’n Ex. V, McFadden Dep. at 114-17.)

Moreover, for the reasons discussed in the sections above, the Court finds that there is clear, convincing and undisputed evidence that the Ostar® process contains all of the elements of:

Claim 2 (dependent claim adding to claim 1 the limitation “wherein some of the dehydrated preparation will absorb moisture from perspiration from the hand during wearing and disassociate from the enhanced glove and condition the hand”);

Claim 3 (dependent claim adding to claim 1 the limitation “wherein the skin-conditioning substance includes a medicinal substance”);

Claim 4 (dependent claim adding to claim 1 the limitation “wherein the skin-conditioning substance is a skin-soothing substance”);

Claim 8 (dependent claim adding to claim 1 the limitation “wherein the applying step includes dipping the glove onto the preparation”);

Claim 25 (dependent claim adding the limitation “[t]he method of claim 1 further for using the glove, the method further comprising the act of adding moisture to the dehydrated preparation only via perspiration by the hand”);

Claim 28 (dependent claim adding the limitation “[t]he method of claim 1, wherein the dehydrated preparation is to be moistened only by perspiration from the hand”);

Claim 29 (dependent claim adding the limitation “[t]he method of claim 1 further for using the glove, the method further comprising the act of adding moisture to the dehydrated preparation, the moisture including perspiration by the hand”);

Claim 35 (independent method claim deleting the limitation “the preparation including a skin-conditioning substance and a liquid carrier, wherein the skin-conditioning substance comprises a skin-moisturizing substance” of claim 1 and adding the limitations “prior to the applying step, arranging the glove inside out, whereby the interior surface of the glove faces outward” and “wherein the glove is turned right side out after the evaporation step”);

Claim 44 (independent method claim deleting the limitation “the preparation including a skin-conditioning substance and a liquid carrier, wherein the skin-conditioning substance comprises a skin-moisturizing substance” of claim 1 and adding the limitation “the preparation including a skin softening substance and a liquid carrier”);

Claim 45 (independent method claim deleting the limitation “the preparation including a skin-conditioning substance and a liquid carrier, wherein the skin-conditioning substance comprises a skin-moisturizing substance” of claim 1 and adding the limitation “the preparation including a skin nourishing substance and a liquid carrier”);

Claim 46 (independent method claim deleting the limitation “the preparation including a skin-conditioning substance and a liquid carrier, wherein the skin-conditioning

substance comprises a skin-moisturizing substance” of claim 1 and adding the limitation “the preparation including a skin emollient substance and a liquid carrier”);

Claim 47 (independent method claim deleting the limitation “the preparation including a skin-conditioning substance and a liquid carrier, wherein the skin-conditioning substance comprises a skin-moisturizing substance” of claim 1 and adding the limitation “the preparation including a skin anti-inflammatory substance and a liquid carrier”).

That leaves method claims 9 and 33 and article claims 10 and 34. Claim 9 depends from claim 1 with the limitation that “the applying step includes spraying the preparation onto the glove.” Claim 33 is an independent claim that contains all of the elements of claim 1 and the spraying limitation of claim 9. Plaintiffs admit that coating a glove by spraying, rather than dipping as in the Ostar® process, would have been obvious to a person of ordinary skill in the art in 1999. (Pls.’ Resp. Def.’s Stmt. Facts ¶ 51.) As such, spraying is considered prior art. *See Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (“‘[P]rior art’ . . . is knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in an art.”).

Claims 10 and 34 claim methods of manufacturing a glove in which “the interior surface of the glove is treated with chlorine prior to the applying step.” Though the Ostar® glove was not chlorinated before it was coated, the parties agree that treating gloves with chlorine would have been obvious to a person of ordinary skill in the art in 1999. (Pls.’ Resp. Def.’s Stmt. Facts ¶ 58.) Plaintiffs claim, however, that it would not have been obvious both to chlorinate and apply a coating to a glove because the two steps “perform the same function” – “reduc[ing] or eliminat[ing] tack.” (Pls.’ Opp’n Ex. Y, McFadden Rebuttal Report at 24-25.)

However, that is precisely the process disclosed in U.S. Patent No. 5,742,943 (“‘943 Patent”), which was issued on April 28, 1998:

[P]owdered gloves are . . . inverted

The inverted glove is then washed to remove the powder and starch from the glove.

...

The washed gloves are then chlorinated. . . .

...

A lubricant solution is then added into the chlorinator containing gloves which are then tumbled for about five minutes. This coats the donning side with the lubricant solution. . . .

The coated gloves are then put into a drier and dried for about ten to fifteen minutes at about 110° F. to dry the donning surface. . . .

(Def.'s Ex. 64, '943 Patent, Col. 10, l. 43-Col. 11, l. 41.) Moreover, the '943 Patent specification says the lubricant solution is applied to a chlorinated glove to give the glove "superior lubricity with respect to wet/damp hand donning," *i.e.*, to reduce tack. (*Id.*, Col. 9, ll. 3-5.) Thus, the record establishes that using both chlorination and a coating on gloves to reduce tack was known to those skilled in the art in 1999. Therefore, the Court holds that claims 10 and 34 are anticipated by prior art. *See Kimberly-Clark Corp.*, 745 F.2d at 1453.

II. Obviousness

Defendant also seeks a declaration that claims 17, 19-21, 24, 30-32 and 36-43 ("aloe claims") are obvious in light of prior art. *See* 35 U.S.C. § 103 ("A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."). Plaintiffs say the Court lacks jurisdiction over defendant's claim for a declaration that the aloe claims are invalid because there is no controversy over them. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (saying that a court has jurisdiction over claims for declaratory relief only if "there is a substantial

controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” (quotation omitted)). Plaintiffs do not assert that defendant’s Polymed glove, which does not contain aloe vera, infringes these claims and have promised not to do so in the future. (*See* Pls.’ Reply Br. Supp. Mot. Summ. J. at 23.) As a result, they say the requisite controversy over these claims is lacking.

Defendant says there is a sufficient controversy because: (1) this suit caused it to stop work on a different, aloe vera-containing glove, for which it had sought FDA approval before this suit was filed; and (2) plaintiffs’ covenant not to sue applies only to defendant’s Polymed gloves. *See Cat Tech*, 528 F.3d at 881 (“[A] party need not have engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment of non-infringement, [but] there must be a showing of ‘meaningful preparation’ for making or using that product.” (quotation omitted)); (Def.’s Sur-Reply Resp. Pls.’ Reply Br. Mot. Summ. J, Ex. 1, Harris Decl. ¶¶ 1-4; Def.’s Opp’n Ex. 121, 510k Abbreviated Notification: Latex Patient Examination Glove dated 10/30/02; Pls.’ Reply Br. Supp. Mot. Summ. J. at 23 (“Plaintiffs covenant that they will not sue Sempermed for any past, present or future infringement of [the aloe] claims by the accused Polymed TLC Glove currently or previously advertised, manufactured, marketed or sold by Sempermed.”)).

Plaintiffs urge the Court to disregard the affidavit and the FDA application defendant offers to support the first assertion because they were submitted after the summary judgment motions were fully briefed. That is true of the affidavit, which defendant submitted with its sur-reply but not, as plaintiffs admit, of the FDA application. (*See* Pls.’ Resp. Def.’s Stmt. Add’l Facts ¶ 211 (“Plaintiffs admit that Sempermed produced a 510(k) application in which the word ‘aloe’ appears”) In any event, because subject matter jurisdiction can be addressed at any stage of the proceedings, *see* Fed.

R. Civ. 12(h)(3) (“If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.”), defendant’s evidence cannot be dismissed as untimely.

Though they frame it as a jurisdictional issue, plaintiffs’ argument is more appropriately viewed as one of waiver. Plaintiffs say, in essence, that defendant waived any argument about the validity of the aloe claims because defendant did not raise the issue in its pleadings, claim charts or expert reports.

The record refutes that contention. Though defendant did not assert invalidity of the aloe claims as a counterclaim, it did raise the issue as an affirmative defense and in its discovery responses. *See* Fed. R. Civ. P. 8(c)(2) (“If a party mistakenly designates a defense as a counterclaim, or a counterclaim as a defense, the court must, if justice requires, treat the pleading as though it were correctly designated”); (Third Am. Answer & Countercl., Second & Seventh Affirmative Def.; Pls.’ Ex. 28, Sempermed’s Resp. & Objections Pls.’ First Set Interrogs.; Pls.’ Ex. 29, Sempermed’s First Supplemental Resp. & Objections Pls.’ First Set Interrogs.; Pls.’ Ex. 30, Sempermed’s Fourth Supplemental Resp. & Objections Pls.’ Interrogs. 4 & 5). Moreover, because defendant contends that the ‘582 Patent discloses and enables only the use of aloe vera, the physical characteristics of aloe vera and the extent, if any, to which it performs the skin-enhancing functions claimed in the ‘582 Patent was extensively addressed by both parties. (*See, e.g.*, Def.’s Stmt. Facts ¶¶ 71-72, 97-100; Pls.’ LR 56.1(a) Stmt. ¶¶ 9, 104, 106-10, 112-21; Pls.’ Stmt. Add’l Material Facts ¶¶ 172-81, 183-88, 192-200; Def.’s Ex. 3, Wickett Dep. at 120-24; Def.’s Ex. 4, Redmond Expert Report at 23-28, 31-32, 41; Def.’s Ex. 82, Wickett Rebuttal Report at 20-22; Def.’s Opp’n Ex. 113, Chou Dep. at 9-16; Def.’s Opp’n Ex. 115, Redmond Sur-Rebuttal Report at 12-15, 19-21, 23, 26-27; Pls.’ Ex. 62, McFadden Rebuttal Report at 6-10; Pls.’ Ex. 69, Chou Dep. at 126-29, 134-38, 143-45; Pls.’ Ex. 75, Chou Decl. ¶¶ 6-7; Pls.’ Ex. 76, McFadden Decl. ¶¶ 5-10; Pls.’ Opp’n Ex. N, Wickett Dep. at 270-73; Pls.’ Opp’n

Ex. V, McFadden Dep. at 71-83; Pls.' Opp'n Ex. W, Lim Dep. at 125-33.) Accordingly, the Court finds that the validity of the aloe claims is properly at issue in this case.

The aloe claims are:

Claim 17: "The article of claim 16 [which, in turn, claims the article of claim 13] wherein the coating consists of dehydrated aloe vera.";

Claim 19: "The article of claim 13 wherein the skin-moisturizing substance comprises aloe vera.";

Claim 20: "The article of claim 13 wherein the skin-moisturizing substance consists of aloe vera.";

Claim 21: "The article of claim 13 wherein the coating consists of dehydrated aloe vera.";

Claim 24: "The method of claim 6 [which, in turn, claims the method of claim 1] wherein the dehydrated preparation consists of dehydrated aloe vera.";

Claim 30: "The method of claim 1 wherein the dehydrated preparation consists of dehydrated aloe vera.";

Claim 31: "The method of claim 1 wherein the skin-conditioning substance and the liquid carrier comprise aloe vera.";

Claim 32: "The method of claim 1 wherein the skin-conditioning substance consists of aloe vera.";

Claim 36: "An article for protecting a hand, the article comprising: a disposable examination glove that is fluid-impermeable; and a coating on a surface of the disposable examination glove, the coating including a dry skin-soothing or skin-moisturizing substance that had undergone dehydration, prior to becoming dry, while on the surface of the disposable examination glove, wherein, the coating contacts a hand during donning of the article onto the hand, and the coating absorbs moisture from perspiration when worn on the hand to form a moistened skin-soothing or skin-moisturizing substance; wherein the disposable examination glove is a single-layer glove; and wherein the coating consists of dehydrated aloe vera";

Claim 37: an independent article claim repeating the elements of claim 36 except the limitations "wherein the disposable examination glove is a single-layer glove" and "wherein the coating consists of dehydrated aloe vera" and adding the limitation "wherein the skin-soothing or skin-moisturizing substance comprises aloe vera";

Claim 38: an independent article claim repeating the elements of claim 37 except the limitation “wherein the skin-soothing or skin-moisturizing substance comprises of aloe vera” and adding the limitation “wherein the skin-soothing or skin-moisturizing substance consists of aloe vera”;

Claim 39: an independent article claim that is identical to claim 38;⁴

Claim 40: “A method of manufacturing an enhanced disposable glove, the method comprising: applying a preparation onto a surface of a fluid-impermeable disposable glove, the preparation including a skin-conditioning substance and a liquid carrier, the surface of the glove to face a hand during wearing of the glove on the hand, the surface hereinafter referred to as interior surface; and evaporating the liquid carrier from the preparation to form a dry dehydrated preparation attached to the interior surface of the glove, so that the dehydrated preparation contacts the hand during wearing of the glove on the hand; wherein in [sic] the glove is made of [sic] single layer prior to the applying step and the dehydrated preparation consists of dehydrated aloe vera.”;

Claim 42: an independent method claim repeating the elements of claim 40 except the limitations “wherein in [sic] the glove is made of [sic] single layer prior to the applying step and the dehydrated preparation consists of dehydrated aloe vera” and adding the limitation “wherein the skin-conditioning substance and the liquid carrier comprise aloe vera.”; and

Claim 43: an independent method claim repeating the elements of claim 42 except the limitation “wherein the skin-conditioning substance and the liquid carrier comprise aloe vera” and adding the limitation “wherein the skin-conditioning substance consists of aloe vera.”

Whether these claims are obvious in light of the prior art depends on: “(1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness.” *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 725-26 (Fed. Cir. 2002). “Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

⁴The record does not explain why the ‘582 Patent contains two identical claims.

Viewed favorably to plaintiffs, the record shows that the relevant art is latex glove making and a person with ordinary skill in that art has two to five years' experience in the development of such gloves and a Bachelor's Degree in science. (Pls.' Stmt. Add'l Material Facts ¶ 222.) It also shows that on April 7, 1999, the priority date to which plaintiffs say the '582 Patent is entitled, people of ordinary skill in the art knew: (1) how to make the Ostar® gloves according to the Ostar® process which, as discussed above, contain all of the elements of claims 1-10, 25-26, 28-29, 33-35 and 44-47 of the '582 Patent; (2) how to make single- and multiple-layer gloves containing, among other things, biocides, lubricants, antiseptics, gels, cleansing agents and other coatings; (3) how to make multiple-layer gloves containing skin-enhancing substances, including almond oil, jojoba oil, Vitamin E oil, olive oil and aloe vera; and (4) that aloe vera has skin-enhancing properties. (See Pls.' Resp. Def.'s Stmt. Facts ¶¶ 40-46; Pls.' Stmt. Add'l Material Facts ¶¶ 197-200; Pls.' Ex. 1, '582 Patent, Col. 1, ll. 41-61; Pls.' Ex. 17, U.S. Patent No. 3,793,059; Pls.' Ex. 62, McFadden Rebuttal Report at 6-8, 28-31, 33; Pls.' Ex. 75, Chou Decl. ¶ 4; Pls.' Ex. 76, McFadden Decl. ¶ 9; Pls.' Ex. 77, U.S. Patent No. 4,775,372; Pls.' Ex. 78, U.S. Patent No. 5,869,072; Pls.' Opp'n Ex. G, U.S. Patent No. 5,133,090; Pls.' Opp'n Ex. H, U.S. Patent No. 6,254,947; Def.'s Ex. 8, McFadden Dep. at 131; Def.'s Ex. 60, U.S. Patent No. 5,549,924; Def.'s Ex. 61, U.S. Patent No. 3,740,262; Def.'s Ex. 64, U.S. Patent No. 5,742,943.) There is no evidence concerning the secondary considerations, and it is unreasonable, given the scope of the prior art, to infer that plaintiffs succeeded where others failed or their purported invention filled a long-felt need. In light of the undisputed facts, the Court holds that it would have been obvious in April 1999 to use aloe vera, alone or in combination with other substances, to coat the inside of a latex glove.

The testimony of Chou and McFadden, who plaintiffs say are experts in the field (*see* Pls.' LR 56.1(a) Stmt. ¶ 111), supports this conclusion. Chou said: "I recognize that the only substance the

‘154 patent [the ‘582 Patent’s ancestor] referred to by name was aloe vera” but “it would naturally occur to anyone skilled in the art in 1999, upon reading the ‘154 Patent that other substances beneficial to the skin could be used.” (Pls.’ Ex. 75, Chou Decl ¶ 6.) She also said:

I did not believe there was anything unique about aloe vera that allowed it to be mixed in a solution, applied to a glove and dehydrated. I am not aware of any literature at the time or now that states that aloe vera is unique in its ability to do this. I believe many other substances could perform in a similar fashion, such as allantoin, vitamin E, glycerol or chamomile to name a few. One of ordinary skill in the art in 1999 would have understood that all of these substances could have been substituted for one another in the dehydrated layer applied to the glove without undue experimentation.

(*Id.* ¶ 7.) Similarly, McFadden said:

If a person of ordinary skill in the art read th[e] specification [of the ‘154 Patent] in its entirety, it would naturally occur to him or her that in addition to Aloe Vera, there would be many other readily available substances that provide similar skin conditioning, skin moisturizing, skin enhancing or skin soothing effects that could be utilized in the ‘154 manufacturing process.

...

[T]he novelty of the ‘154 Patent [w]as the process of applying a layer of dehydrated substance beneficial to the skin on the interior of the glove. . . . Whether that substance was aloe vera or anything else was not nearly as important as the process by which it was attached.

... One of ordinary skill in 1999 would not have viewed the actual substance as novel because it would have been understood that any substance that provided skin conditioning, moisturizing, soothing or enhancing effects could be used, including aloe vera.

(Pls.’ Ex. 76, McFadden Decl. ¶¶ 6, 9-10.) Coupled with plaintiffs’ assertion that the skin-enhancing properties of aloe vera were known in the art in 1999, Chou and McFadden’s testimony that it would have been obvious to use other skin-enhancing substances is virtually an admission that using aloe vera would have been obvious as well.

In sum, the Court holds that all of the claims of the '582 Patent are invalid. Claims 1-16, 18, 22-23, 25-29, 33-35 and 44-51 are anticipated by the prior art Ostar® glove and manufacturing process. Claims 17, 19-21, 24, 30-32 and 36-43 are obvious in light of the prior art. Given this holding, the Court need not address the other bases for invalidity urged by defendant or the issues of inequitable conduct or infringement. Because the Court grants defendant's motion for summary judgment, plaintiffs' cross-motion for summary judgment is necessarily denied.

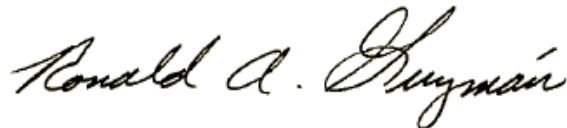
Conclusion

For the reasons set forth above, the Court overrules plaintiffs' objections to Magistrate Judge Nolan's discovery ruling; grants in part and denies in part plaintiffs' motion to strike testimony of defense expert Redmond [doc. no. 230], and grants in part and denies in part defendant's motion to strike sections of plaintiffs motion for summary judgment [doc. no. 223]. The Court finds that there is no genuine issue of material fact with respect to the claims plaintiffs assert against defendant or the counterclaims defendant asserts against plaintiffs, and defendant is entitled to judgment as a matter of law. Therefore, defendant's corrected motion for summary judgment [doc. no. 187] is granted and plaintiffs' motion for summary judgment [doc. no. 199] is denied. This case is terminated.

SO ORDERED.

ENTERED:

March 12, 2009



HON. RONALD A. GUZMAN
United States District Judge